

## **REMARKS**

Claims 7-9, 11 and 12 are pending and under consideration. In the instant amendment, Claims 11 and 12 have been amended. Claims 7-9 stand as allowed.

### **I. AMENDMENTS TO THE CLAIMS**

Claims 11 and 12 have been amended to recite that “. . . the HFE polypeptide and the human  $\beta_2m$  are in a secreted soluble complex . . .” The amendments are fully supported by the specification, for example, beginning at page 13, line 11 to page 14, line 35.

Applicants believe that entry of the amendments to the claims is proper under 37 C.F.R. §1.116 because the amendments are believed to place Claims 11 and 12 in condition for allowance.

Entry of the amendments to the claims is respectfully requested.

No amendment fee is believed to be due.

### **II. REJECTION OF CLAIM 11 UNDER 35 U.S.C. § 103(a)**

Claims 11 and 12 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over either U.S. Patent No. 6,025,130 to Thomas *et al.* (“the ’130 patent”) or U.S. Patent No. 6,140,305 to Thomas *et al.* (“the ’305 patent”). Applicants respectfully traverse the rejection of Claims 11 and 12, and respectfully submit that neither the ’130 patent nor the ’305 patent teaches or suggests each and every element of amended Claim 11 or amended Claim 12.

The ’305 and ’130 patents describe using  $\beta_2$  microglobulin for affinity chromatography of full-length HFE polypeptide, that is, where  $\beta_2$  microglobulin is attached to an inert matrix prior to forming a complex with HFE polypeptide. *See, e.g.*, ’305 patent at column 24, lines 25-48. The full length HFE polypeptide discussed in the cited documents is an integral membrane protein having a transmembrane domain and requiring detergents to remain in solution as discussed, for example, in the ’305 patent at column 24, lines 18-23, as well as in the instant specification at page 7, lines 20-25. However, neither the ’130 patent nor the ’305 patent teaches or suggests an isolated HFE polypeptide in a secreted soluble complex with human  $\beta_2$  microglobulin suitable for administration to a subject, as recited in Claims 11 and 12.

In response to arguments presented in Applicants' Amendment and Response of August 12, 2005, the Patent Office stated:

Applicant argues that the prior art does not properly teach a "soluble" form of the complex because the one skilled in the art understands that "**secreted proteins are soluble** in aqueous solvents even in the absence of lipids or detergents" (emphasis added by Examiner for clarity). . . . However, Applicant's claims are not drawn to "secreted" proteins, as put forth in the arguments.

November 21, 2005, Office Action, pages 3-4.

With the amendments to Claims 11 and 12, the recited HFE polypeptide and  $\beta_2$  microglobulin complexes are in a secreted form, *inter alia*. As discussed above and in Applicants' Amendment and Response of August 12, 2005, the patent documents cited by the Patent Office do teach or suggest secreted soluble complexes of HFE polypeptides and human  $\beta_2$  microglobulin suitable for administration to a subject.

In view of the foregoing, and for the reasons provided in the Applicants' Amendment and Response of August 12, 2005, Applicants respectfully submit that the Patent Office has failed to establish that the cited references teach or suggest each and every element of amended Claim 11 or Claim 12.

Accordingly, Applicants respectfully request that the rejection of Claims 11 and 12 under 35 U.S.C. § 103(a) be withdrawn.


### CONCLUSION

In light of the above amendments and remarks, Applicants respectfully request that the Examiner reconsider this application with a view towards allowance.

No fees, other than that for the petition for an extension of time, are believed to be due. However, the Commissioner is hereby authorized to charge any required fee, fee under 37 C.F.R. § 1.17, any underpayment of fees, or credit any overpayment to Jones Day Deposit Account No. 50-3013 (referencing 043018-999098) in connection to this Amendment and Response.

Respectfully submitted,

Date: March 20, 2006

  
\_\_\_\_\_  
Roger C. Rich 54,398  
(Reg. No.)  
For: Nikolaos C. George (Reg. No. 39,201)

**JONES DAY**  
222 East 41st Street  
New York, New York 10017  
(212) 326-3939